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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,990	07/08/2003	Yukiko Ishikawa	US-1520	5154

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EXAMINER	
VOGEL, NANCY S	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,990	ISHIKAWA ET AL.	
	Examiner	Art Unit	
	Nancy T. Vogel	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 08 July 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 105,12/04,7/04,12/.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-10 are pending in the case.

Information Disclosure Statement

Receipt of Information Disclosure Statements on 1/6/05, 12/1/04, 7/8/04, 12/15/03, 10/7/03 are hereby acknowledged. Those references which are struck through are either duplicates (marked as such), or are non-publicly available patent applications listed by serial number. These applications have been considered, but would not be appropriate to be printed on the face of any patent that issues from the instant application.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "an ArcA protein does not normally function". This could be interpreted at least two ways, i.e. the bacteria is modified such that (1) the ArcA protein does not usually function, only functioning (i.e. having wild type activity) under certain conditions, or (2) the ArcA protein does not function normally, i.e. it is modified such that it (always) behaves in a different way from the wild type ArcA protein. Clarification is required. In the interest of compact prosecution the claim has been examined using option (2) above.

Claims 2-4 are further vague and indefinite in the recitation of "wherein the ArcA protein that normally functions is a protein...". Since the claims are dependent on claim 1, and claim recites "an ArcA protein does not normally function", it is unclear whether the ArcA recited in claims 2-4 is a second ArcA protein, different from the ArcA that "does not normally function", which is present in the bacterium recited in claim 1, or whether the claims are setting forth the identity of the ArcA protein which was present before mutation that resulted in the ArcA protein functioning non-normally (i.e. the wild type ArcA). In the interest of compact prosecution, claims 2-4 have been examined as if the recited "ArcA that normally functions" refers to the non-altered version of the ArcA protein that does not normally function recited in claim 1, before the alteration resulting in the non-normal function.

Claim 6 is vague and indefinite in the recitation of "DNA hybridizable with the nucleotide sequence of the nucleotide numbers 101 to 817 of SEQ ID NO:31 or a probe that can be produced from the nucleotide sequence under the stringent condition and coding for a protein that improves an ability to produce a target substance when the

protein does not normally function compared with the case where the protein normally functions". It is not clear what is intended by this phrase; for instance, how is a probe is "produced from a nucleotide sequence under the stringent condition and coding for a protein..."? The claim is unclear and the intended metes and bounds cannot be determined.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, and 8-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim any gamma-proteobacterium having an ability to produce a target substance and modified so that an ArcA protein does not normally function. The claims read on a broad genus of bacteria having the altered ArcA protein.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, ie. structure or other physical and/or chemical properties, by function characteristics coupled with a known or

disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant case, the specification does not sufficiently describe a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics.

Applicant claims any gamma-proteobacterium having the ability to produce a target substance and modified so that an ArcA protein does not normally function. The specification only provides teaching regarding two such bacteria, which are E. coli and Pantoea ananatis, which have been modified such that an ArcA protein does not normally function. There is no teaching of a representative number of bacteria belonging to the large group of gamma-proteobacteria, and the ArcA encoding genes therefrom. It is noted that the bacteria contained within the group of gamma-proteobacteria include such diverse types as photosynthetic purple sulfur bacteria, the intracellular parasitic Legionellales, Vibrio and Pasteurellales. There is no disclosure of structural identifying characteristics of the ArcA protein or the gene encoding it, with sufficient identifying characteristics, such that a person skilled in the art would recognize that the invention had possession of the claimed invention. In claims to genetic material, which is indirectly the case in the instant claims, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA", without more, is not adequate written description of the claimed genus, since it does not distinguish genes from others except by function, and does not specifically define any of the genes that fall within its definition, or describe structural features commonly possessed by members of the

genus that distinguish them from others; accordingly, naming the type of material generally known to exist, in absence of knowledge as to what that material consists of, is not description of that material (Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406). In the instant case, the bacteria modified such that an ArcA protein does not function normally has been defined only by a statement of function that broadly encompasses ArcA activity, which conveys no distinguishing information about the identity of the claimed ArcA protein, such as its relevant structural or physical characteristics. The skilled artisan cannot envision what bacteria meet the limitations set forth in the claims, since the ArcA protein and the gene encoding it have been identified only in the E. coli and P. ananatis bacteria. Structural identifying characteristics of ArcA proteins from other bacteria are not disclosed. The ability to **potentially** identify the claimed subject matter is not sufficient to meet the written description requirement, since the subject matter of the claims is not adequately described in the specification. Therefore, one of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only two members of this genus is not representative of the genus and is insufficient to support the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Cotter et al. (FEMS Microbiology Letters, Vol. 91, No. 1, pp. 31-36, 1992) (cited by applicants).

Cotter et al. disclose E. coli comprising a deletion of the arcA gene, which encodes a protein ArcA, and therefore the protein does not normally function (see page 32, paragraph 1, right column, and Table 1). Said E. coli inherently has the ability to produce target substances which are L-amino acids, including lysine, glutamic acid, and arginine.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Iuchi et al. (Proc. Natl. Acad. Sci. USA, Vol. 85, No. 6, pp. 1888-1892, 1988) (cited by applicants).

Iuchi et al. disclose E. coli comprising a deletion of the arcA gene, which encodes a protein ArcA, and therefore the protein does not normally function (see page 1891, left column, last paragraph – right column, second paragraph, and Tables 1 and 2). Said E. coli inherently has the ability to produce target substances which are L-amino acids, including lysine, glutamic acid, and arginine. The reference discloses a method of producing a target substance, comprising culturing E. coli having a mutation in the arcA gene which encodes ArcA, in a medium to produce and accumulate the target

substance in the medium or cells and collecting the target substance from the medium or the cells (see Table 2, see page 1889, first column, paragraph 2- column 2, first paragraph).

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Nystrom et al. (EMBO J., Vol. 15, No. 13, pp. 3219-3228, 1996) (cited by applicants).

Nystrom et al. disclose E. coli strain comprising a deletion of the arcA gene, in which the ArcA protein does not function normally (see page 3220, right column – page 3221, end of right column). The reference discloses a method of producing a target substance, comprising culturing E. coli having a mutation in the arcA gene which encodes ArcA, in a medium to produce and accumulate the target substance in the medium or cells and collecting the target substance from the medium or the cells (see Fig. 3, see page 3226, first column second paragraph – second column, second paragraph).

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Sugimoto et al. (US Patent 5,919,614).

Sugimoto et al. disclose an E. coli wherein the ArcA protein that normally functions is defined as a protein having the amino acid sequence of SEQ ID NO:32 including substitution deletion, insertion or addition of one or several amino acids and improving an ability to produce a target substance which is glutamic acid, when the

protein does not normally function in the E. coli compared with the case where the protein normally functions (columns 16-17). It is noted that due to the open language "a protein having the amino acid sequence of SEQ ID NO:32 including substitution, deletion, insertion or addition of one or several amino acids", the sequence of the recited protein may be virtually any sequence, and therefore the E. coli comprising a mutated enzyme phosphoenopyruvate carboxylase disclosed in the reference, which is mutated such that the E. coli yields more target substance, i.e. glutamic acid, in the presence of the mutant as compared to when the wild type protein is present, anticipates the claim.

Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Cervin et al. (WO 2004/033421) (cited by applicant).

Cervin et al. disclose a bacteria, including E. coli or P. ananatis having the ability to produce a target substance, which includes amino acids, and which is modified so that an ArcA protein does not function normally (page 4 first paragraph). The gene encoding ArcA, i.e. arcA, may be deleted (page 6, first paragraph). The reference discloses a method for producing a target substance comprising culturing the bacteria and collecting the target substance (see claims).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

N. T. Vogel

Nancy T. Vogel, Ph.D.
Patent Examiner